

# Annual Review 2020



*Together, we're finding  
answers to cancer.*

Supported by



## What we do

Since Cancer Trials Ireland was established in 1996, more than 15,000 patients have participated in over 350 of its trials. Almost all cancer treating specialists in Ireland are members of Cancer Trials Ireland.

The organisation's trials are carried out in 14 hospital-based Cancer Trials Units (CTUs) across the country, supported by a central team of clinical researchers, project managers, data managers and other experts. As well as managing its own in-house academic trials, Cancer Trials Ireland also works with global pharmaceutical companies and international collaborative research groups, which generates substantial inward investment and access to innovative treatments for cancer patients.

Cancer is a global health issue. The World Health Organisation reports that cancer is the second leading cause of death globally and is responsible for an

estimated 9.6 million deaths in 2018. Globally, about 1 in 6 deaths is due to cancer.

According to the 2019 Annual Report from the National Cancer Registry of Ireland (NCRI), cancer is the most common cause of death in Ireland, accounting for almost 31% of deaths in 2016. The approximate annual average of deaths from invasive cancer occurred from 2014-2016 and was 9,020. It is estimated that about 35,440 invasive cancers were diagnosed annually in 2017, 2018 and 2019 in Ireland.

Taking the ageing population into account, NCRI projections (2019) show cancer rates have stabilised or even declined in recent years. Nevertheless, projected population growth and ageing in Ireland will result in a substantial increase in the number of cancer cases in the coming decades, potentially doubling from current levels by 2045.

## Vision & Mission

The Board rotates at the AGM every year as per the Constitution. The Board is chaired by Dr. Jonathan Westrup, appointed in 2014 and he is a strategy and governance expert. The Board meets 5 times per year and permanent agenda items include reports from Clinical Executive Committee and Audit Committee

The vision at Cancer Trials Ireland is focused on one primary purpose. To provide every patient with cancer access to high-quality and potentially life altering cancer trials and make Ireland a highly attractive location to open cancer trials. Our mission is to discover new diagnostics and treatments that will extend and enhance the lives of the millions of people who are diagnosed with cancer each year.

In order to achieve this vision, Cancer Trials Ireland must undertake translational and clinical cancer trials which investigate all disease areas and it must have in place the organisational capability to do so.

The 5 strategic pillars are the key to enable Cancer Trials Ireland to achieve this vision and mission:

1. Governance
2. Profile
3. Funding Model
4. Operational Capabilities
5. Clinical Capabilities

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## 2020 at a glance

In 2020, approximately 20% of the open trials are in-house academic trials (2019: 26%) funded by the grants received from the Health Research Board and the Irish Cancer Society. 34% (2019: 45%) of these open trials involved collaboration with cancer research groups and/or are Investigator Initiated Studies which are funded through pharmaceutical companies. The 46% balance of open trials are run by international pharmaceutical companies in Irish hospitals (2019: 29%) where staff at the General Central Office do limited work and receive little or no support. However, to capture a complete picture of cancer clinical trials in Ireland, we adopt these trials into our portfolio.

During 2020, the 11 hospital based cancer trials research units we fund directly (plus the 5 research units linked to these hospitals) were working on 268 cancer trials involving more than 6,000 patients. All the trials involved a highly cooperative effort between investigators, research teams in each hospital based research unit and the staff at our central office

Of the 95 trials that were open and recruiting patients during 2020:

- 20% were **In-house** academic trials (which Cancer Trials Ireland initiates, manages, sponsors and monitors) and are generally funded by the grants received from the Health Research Board (HRB) and the Irish Cancer Society or pharmaceutical companies.
- 34% were **Collaborative** trials which involve working closely with other cancer research groups around the world.
- 46% were **Industry** trials which were initiated and managed by pharmaceutical companies and adopted into our trials portfolio.

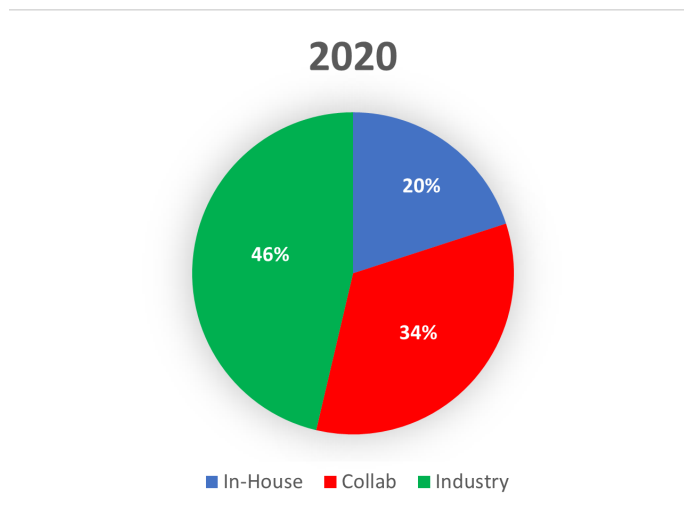


Fig 1: % of Open trials which were In-house, Collaborative and Industry trials.

There were 24 articles published in peer-reviewed journals and 15 oral and poster abstract conference presentations based on the findings of trials in which Members of Cancer Trials Ireland are, or have been, involved.

We were involved in 85 collaborations with pharmaceutical companies, collaborative groups and universities around the world.

Membership, which is open to Medical oncologists, Radiation oncologists, Surgical oncologists, Haematologists and Research Specialists was 549, with 43 new Members admitted during 2020. Membership includes seven affiliated universities, and 14 major affiliated hospital-based research units, which together treat more than 20,000 people with cancer annually in Ireland.

## Chairman's message



**Dr. Jonathan Westrup**

I am delighted to introduce our Annual Review for 2020.

2020 was, as for many other sectors a challenging year for Cancer Trials Ireland. The pandemic impacted revenue, trial monitoring, and plans to open new trials. The organisation's ability to work in person in the office was also severely impacted. Nevertheless, cancer trials Ireland delivered a strong and flexible performance made possible by the commitment of staff who endured a 20% pay cut for a period of three months.

In spite of these challenges, CTI still managed to open new trials, including a European sponsor for an international prostate cancer trial, and a new trial for patients with pancreatic cancer. The year culminated with the whole team, staff and board, contributing to a quality HRB application for the next five years - an application that I am delighted to report was successful.

This is my last message as chair of Cancer Trials Ireland. I want to thank Eibhlín and her team, the network of physicians and support staff who make cancer trials possible. I particularly wish to thank my colleagues on the Board of Cancer Trials Ireland since 2014. They have continually demonstrated a huge level of commitment, and have overseen a significant improvement in the organization's governance across that timeframe.

## Our Board

The Board rotates at the AGM every year as per the Constitution. The Board is chaired by Dr. Jonathan Westrup, appointed in 2014 and he is a strategy and governance expert. The Board meets 5 times per year and permanent agenda items include reports from Clinical Executive Committee and Audit Committee, Governance, Strategy, Conflict of Interest Declarations and Finance. In 2020, the Board met 5 times. (2019: 5)

The members of the Board are qualified to hold their position and represent a range of skills; governance, patient advocate, clinical oncologists, radiation oncologists, industry representative, finance and National Cancer and Control Programme (NCCP) representative. In 2018 the Board appointed a new subgroup called the Patient Consultant's Committee (PCC) set up to integrate the patient voice and experience in the governance structure of the organization.

The Clinical Executive Committee (CEC), Scientific Management Group and Disease Specific Sub-Groups monitor progress on the ongoing clinical trials, make decisions on the adoption of new trials to the portfolio and the CEC reports to the Board of Directors through its Chair; Prof. Bryan Hennessy, Clinical Lead.

The Audit Committee is a subcommittee of the Board and was established in the summer of 2016 and met 7

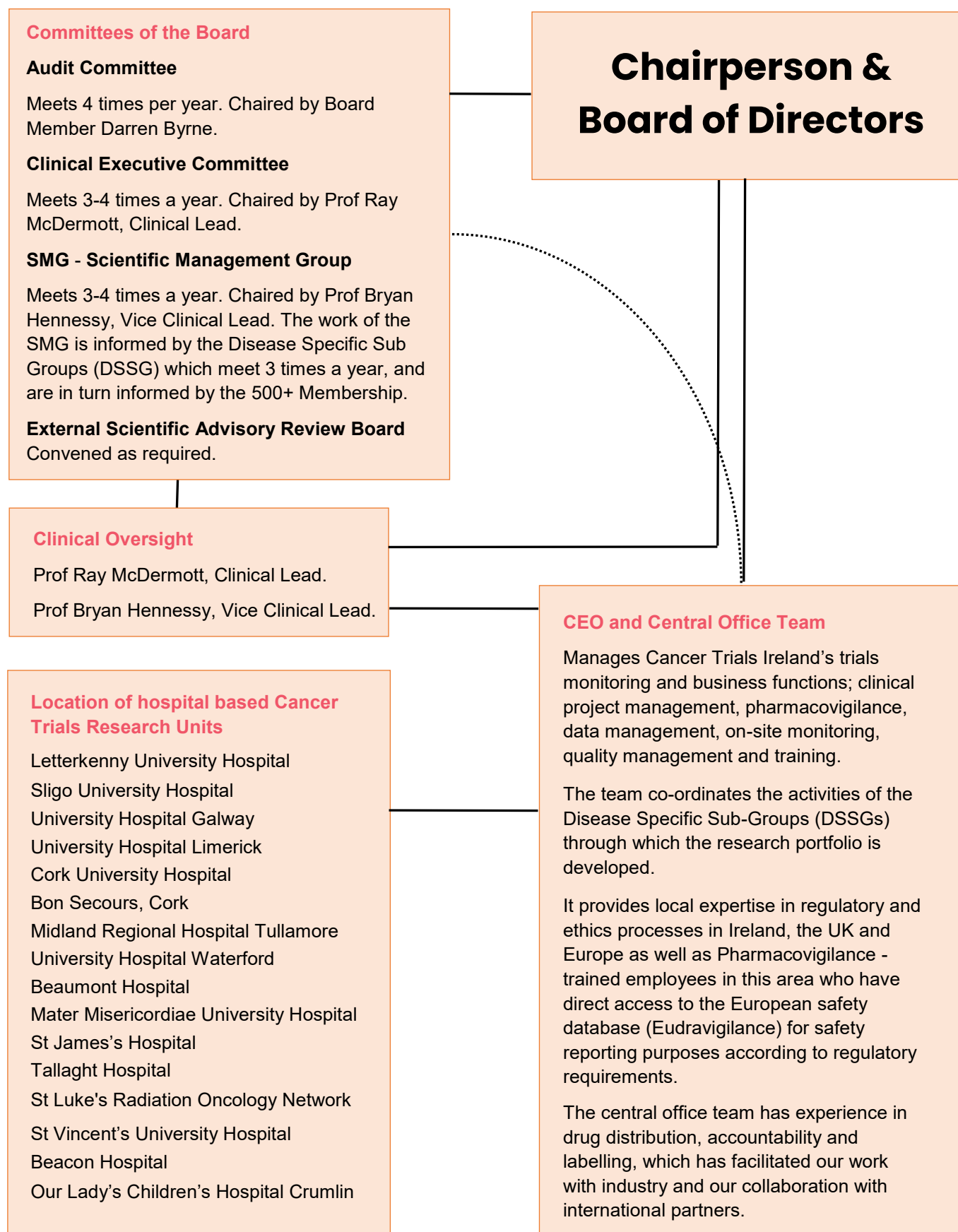
times in 2020 (2019: 4) Darren Byrne is the chair of the Audit Committee and member of the Board of Directors.

- Dr. Jonathan Westrup (Chairman)
- Dr Ruth Barrington (elected Nov 18th 2020)
- Darren Byrne
- Dr. Jerome Coffey
- Dr. Leisha Daly (Resigned Nov 18th 2020)
- Berchmans Gannon (Resigned Nov 18th 2020)
- Diane Hanly (Resigned Nov 18th 2020)
- Prof. Bryan Hennessy
- Patrick Kivlehan (elected Nov 18th 2020)
- Prof. Ray McDermott
- Rory Montgomery (elected Nov 18th 2020)
- Paula Murphy (elected Nov 18th 2020)
- Dr. Robert O'Connor
- Evelyn O'Rourke (Resigned Nov 18th 2020)
- Deirdre Somers (elected Nov 18th 2020)
- Prof John Crown (Resigned Nov 18th 2020)

**Secretary:** Robert Cosgrave



## How we are organised



## From our CEO



**Eibhlín Mulroe**

The year began well, when in March, I was part of an Inter Trade Ireland delegation joined by the US Ireland R&D Partnership to Washington DC. We met with Dr Ned Sharpless, Dr Bill Dahut and team at the National Cancer Institute. The main focus of our engagements was to push for and re-establish the Memorandum of Understanding between the Republic of Ireland, Northern Ireland and the National Cancer Institute in America. That was an agreement that allowed us to cement cross border clinical trials, education and training for nursing and clinicians, so we are keen to re-establish that after it lapsed in 2016. Karen McCallion, InterTrade Ireland, Prof Mark Lawler, Queens University Belfast, Dr Bill Dahut, NCI and I had been working up to this meeting for 2 years.

That was my last action abroad before the pandemic got its grip on Ireland. The pandemic caused us to cancel our DSSG meetings for the first time, and along with it a much-needed stakeholder event focusing on GDPR and health research regulation issues. We were able to re-establish individual DSSG's in the summer and we had a full autumn program that we managed to hold remotely, and which was correspondingly attended very well.

We continue to bring value to our members via new investigator training sessions and stakeholder sessions. In October we facilitated a session on the new HRB funding model. That funding model drove a comprehensive grant application process at the end of the year.

2020 has been a year like no other and we have all had professional and personal challenges with COVID 19. I want to take this opportunity to thank the men and women of Cancer Trials Ireland who weathered the storm together. This is the most collaborative place to work at the best of times but when the going got tough, we pulled together. To all our hospital site staff, to the staff at our General Central Office and to our Leadership Team, your values and commitment to patients continues to inspire me and keep us going.

But I want to finish by remembering a special friend, and almost a year to the day when he helped raise 2.6 million for pancreatic cancer trials, Pat Smullen passed away. His passing triggered another wave of support for Cancer Trials Ireland and an outpouring of public recognition for his life and work. We wrote a letter commemorating his fundraising elements which were broadcasted on television, radio and print media. A copy of that letter is published in this report today. Thank you for everything you did Pat and thank you Frances Crowley who continues to support us in his name.

## From our Clinical Lead



**Prof Ray McDermott**

2022 is my first year if not my first time as clinical lead for Cancer Trials Ireland. When I came into the role, I set out my vision for what I wanted to achieve in the October DSSG digest. What does that entail? Some things must remain the same, and some must change. What is core to us is that we continue to provide new treatments for patients that otherwise wouldn't be available. That's why the organization was founded back in the 90s, and that's a commitment we stick to today.

The second thing that won't change is our focus on investigator led trials. These are the studies that answer questions that are valuable if not necessarily profitable, and they're a very important part of the work that we do.

(..continued from p6) But other things will change, whether or not we may wish it. There is a new HRB grant and the new HRB grant cycle, which now last five years. Applying for this required Cancer Trials Ireland to partner with an academic institution (university) and so after accepting applications, and undergoing a review, we settled on a partnership the Royal College of Surgeons Ireland. RCSI submitted a quality proposal that led to a significant HRB application process between ourselves and RCSI.

The model allows for core funding for the first time allowing us to fund staff and also indeed to work on in some industry trials based on unmet need and other factors. And in contrast to previous years, the funding is multiannual, allowing for more long-term planning.

In closing, I want to thank my colleague Brian Hennessy, the outgoing clinical lead. I want to salute and recognize the commitment he made with for more than eight years, both as Vice clinical lead and then as clinical lead and even in an interim period as Vice clinical lead after I came on board. Thank you, Brian, for all that you have done for the organization.

## Achievements & Performance 2020

- In 2020, Cancer Trials Ireland applied of the Health Research Board Cancer Trials Network Call with the Royal College of Surgeons as the Host Institution. In 2021, the HRB communicated that the application was successful and will award €6.9m over 5 years from Jan 2022 , subject to contracting.
- Despite the Covid Pandemic, Cancer Trials Ireland ran the 5th successful externally funded Just Ask Your Doctor public information campaign communicating with the public and members on radio and media interviews on the value of cancer trials. This included launching a new website for the organisation.
- Cancer Trials Ireland advocacy activities in 2020 included petitioning the Minister for Health to enact legislation to enable the National Research Ethics Committee.
- In 2020, the Pat Smullen Fund Committee met a number of times to review applications and approve activities in the field of pancreatic cancer. There are four studies underway thanks to the €2.6m raised in 2019.
- Cancer Trials Ireland facilitated regular Stakeholder Engagement and Patient Consultants Committee (PCC) meetings in 2020 and appointed a new chair, Patrick Kilvehan.
- The CEO of Cancer Trials Ireland led a delegation with government representation from the Republic of Ireland and Northern Ireland to the National Cancer Institute, Washington DC (March 2020). The agenda of the meeting focused on signing a new MOU between Ministers for Health and NCI. The signing took place in March 2021 and launched by the Taoiseach.



US Ireland Partnership, NCI, Cancer Trials Ireland and the Northern Ireland Cancer Trials Network in Washington DC, March 2020



## Performance metrics

- **In line with best practice among similar international collaborative research groups, we use a series of recognised metrics to measure our performance.**
- **Our performance against these metrics is outlined on pages 9 to 23.**

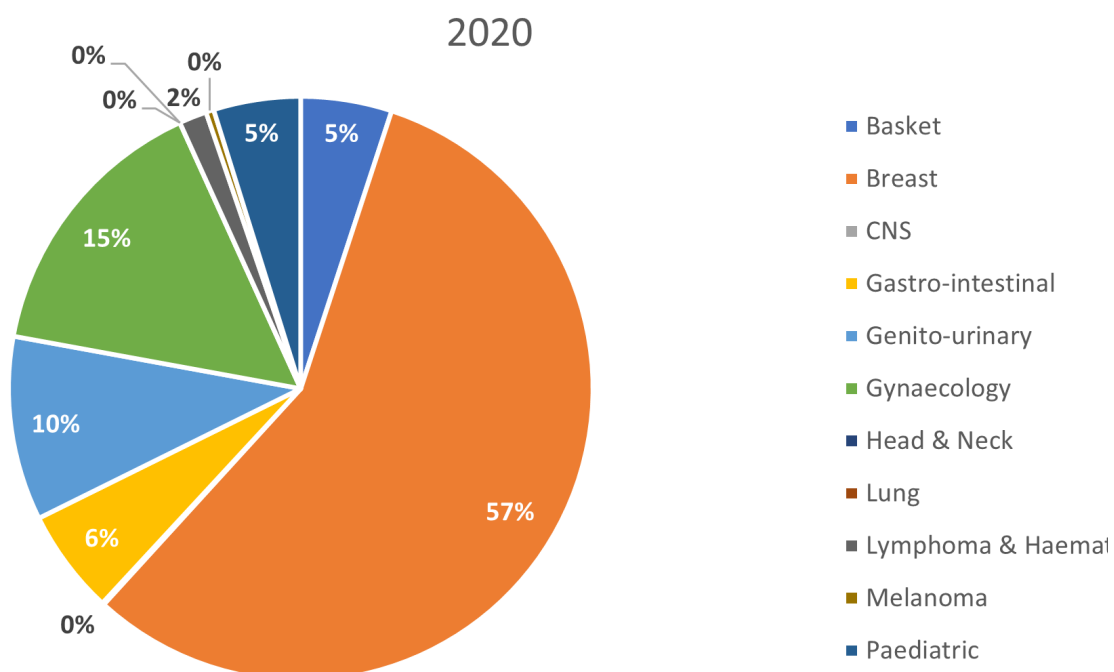
No	Performance Metric	Explanation
1	Accrual	Refers to the number of patients recruited to a trial.
2	Trials portfolio	The number and type of trials in our portfolio.
3	Cancer trials research unit monitoring	Monitoring activity of cancer trials research units includes a broad range of activities conducted from trial commencement until close-out.
4	Audits	The numbers of days spent preparing for and conducting audits and follow-up activity as well as active participation in external sponsor audits and regulatory inspections.
5	Training	The number of training courses conducted and attended.
6	Membership	The number of Members of Cancer Trials Ireland.
7	Participation	Attendances at scientific meetings, International Meetings, and trials introduced and developed by local Principal Investigators (PIs).
8	Publications	The number of publications in peer-reviewed journals and abstracts accepted at top level international.
9	Plans for future period	How Cancer Trials Ireland will adapt to funding changes.



## Accruals

- This metric records the number of patients recruited, or accrued, to all type of trials by disease area.

### By disease area (percentage)



### By disease area (accrual numbers)

**NOTE:** There were also 126 accruals to Non-CTRIAL studies (not included in this chart)

Disease area	2020
Basket	46
Breast	518
CNS	1
Gastro-intestinal	53
Genito-urinary	93
Gynaecology	140
Head & Neck	0
Lung	0
Lymphoma & Haematology	14
Melanoma	4
Paediatric	44
Total	913

Patients were also accrued to a breast cancer biobank.

2020 Biobanking (breast)	286
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## Trials portfolio

This metric records the number and type of trials open and in development during 2020. In-house trials and Collaborative trials (which involve research organisations in other countries) were an important area of focus during 2020. Both In-house trials (which are funded by either HRB, Irish Cancer Society and other supports and/or directly by pharmaceutical companies) and Collaborative trials, are fully supported by our central office clinical, professional, operations and administrative teams. The third type of trials included in our portfolio are Industry trials. While these trials are carried out in the various cancer trials research units, central office staff are minimally involved.

**Table 1**

Disease Area	2017	2018	2019	2020
Basket	6	6	5	9
Breast	68	54	57	45
CNS	5	5	5	5
Gastro-intestinal	33	43	40	31
Genito-urinary	44	44	46	42
Gynaecology	8	13	16	14
Head & Neck	8	9	11	11
Lung	45	36	34	30
Lymphoma & Haematology	31	27	31	30
Melanoma	11	10	12	8
Paediatric	29	40	38	43
<b>Total No of active trials*</b>	<b>288</b>	<b>287</b>	<b>295</b>	<b>268</b>

Table 1 shows the total number of trials active in a particular disease group. 'Active' means trials in development, open, in treatment, in follow-up.

**Table 2**

Disease Area	2017	2018	2019	2020
Basket	3	4	4	7
Breast	21	14	13	13
CNS	2	1	2	2
Gastro-intestinal	14	8	10	14
Genito-urinary	18	16	12	13
Gynaecology	7	5	7	8
Head & Neck	3	4	0	2
Lung	15	13	10	5
Lymphoma & Haematology	12	7	6	7
Melanoma	5	3	0	2
Paediatric	20	26	26	22
<b>Total No of active trials*</b>	<b>120</b>	<b>101</b>	<b>90</b>	<b>95</b>

Table 2 shows the total number of trials open to accrual only.

## Collaborations with international research groups

A large part of the 2020 portfolio of studies in development, open and in follow up studies originate from successful collaborations with international groups.

- **ABCSG** - Austrian Breast and Colorectal Cancer Study Group
- **AIEOP** (Italy) - Associazione Italiana di Ematologia e Oncologia
- **ANZUP & UoSydney** - The Australian and New Zealand Urogenital and Prostate (ANZUP) Cancer Trials Group & University of Sydney
- **BC Cancer** - British Columbia Cancer
- **BCNI** - Blood Cancer Network Ireland
- **BIG/BCT** - Breast International Group
- **Bristol Royal Hospital**
- **CRUK** - Cancer Research UK
- **CCTG** - Canadian Cancer Trials Group

## (collaborations continued)

- **CCRI** (Austria) - St Anna Children's Cancer Research Institute Vienna
- **COG** - Children's Oncology Group
- **Dutch Childhood Oncology Group**
- **DCOG** - Dutch Gynaecology Ibcology Group
- **DSCLL** - Deutsche Studiengruppe CLL
- **ECOG-ACRIN** - Eastern Cooperative Oncology Research Group and American College of Radiology Imaging Network
- **ENGOT** - European Network of Gynaecological Oncological Trials Group
- **EMN** - European Melanoma Network
- **EORTC** - European Organisation for Research & Treatment on Cancer
- **Erasmus Medical Centre**
- **ETOP** - European Thoracic Oncology Platform
- **Findazione Michelangelo**
- **GBG** - German Breast Group
- **GEICAM** - Grupo Español de Investigación en Cáncer de Mama
- **GOSH (UK)** - Great Ormond Street Hospital for Children
- **Gustave Roussy Cancer Campus Paris**
- **GERCOR** - Groupes Cooperateurs en Oncologie
- **Hopp Children's cancer centre Heidelberg**
- **HOVON** - Hemato-Oncologie voor Volwassenen Nederland
- **IBCSG** - International Breast Cancer Study Group
- **IIS Sanitaria La Fe** - Health Research Institute Hospital La Fe Spain
- **IJB** - Institut Jules Bordet
- **IRCCS** - Fondazione Istituto Nazionale Tumori, Milano
- **ITCC** - Innovative Therapies for Children with Cancer
- **Karolinska University Hospital**
- **Lawson Health Research Institute (Canada)**
- **Movember**
- **MRC** - Medical Research Council
- **NRG Oncology** - Incorporating National Surgical Adjuvant Breast and Bowel Project (NSABP); the Radiation Therapy Oncology Group (RTOG); the Gynecologic Oncology Group (GOG)
- **NSABP Foundation Inc**
- **PCCTC** - Prostate Cancer Clinical Trials Consortium
- **PrECOG** - Sister Foundation of ECOG
- **Royal Marsden NHS Foundation Trust**
- **SPCG** - Scandinavian Prostate Cancer Group
- **SIOPE** - European Society for Paediatric Oncology
- **SWOG** - Southwest Oncology Group
- **TROG** - Trans-Tasman Radiation Oncology Group
- **UCL** - University College London
- **University Hospital Freiburg**

## (collaborations continued)

- **University Hospital Muenster, GER**
- **University of Birmingham**
- **University of Edinburgh**
- **University of Leeds**
- **University of Liverpool**
- **UPCI - University of Pittsburgh Cancer Institute**
- **Walton Centre NHS Foundation Trust**

### Specific collaborations during 2020

**ANZUP – The Australian New Zealand Urogenital and Prostate Cancer Trials Group.** We continue our active interaction with ANZUP with the set-up of another large prostate cancer trial, DASL, a randomized phase 3 trial of adding darolutamide to radiation and androgen deprivation therapy in high risk, clinically localized prostate cancer. We will be the EU sponsor of this trial, which will open in Irish and UK sites. The previous two large international phase III prostate cancer trials (ENZAMET and ENZARAD) are still in follow up and first results have been presented at ASCO and published in the New England Journal of Medicine.

**CCTG – Canadian Cancer Trials Group.** In 2014 we started a new collaboration with CCTG with the SHAPE study, a surgical study for low-risk early-stage Cervical Cancer, which is now in follow up. We were able to another CCTG radiotherapy study, TALOR RT, for low risk node positive Breast Cancer, which will open in early 2022.

**DSCLL – Deutsche Studiengruppe CLL.** After successful running the CLL13 study in Ireland, which is now in follow-up, we are opening the CLL17 study, a phase 3 multicenter, randomized trial of Ibrutinib Monotherapy versus fixed-duration Venetoclax plus Obinutuzumab versus fixed-duration Ibrutinib plus Venetoclax for in patients with previously untreated chronic Lymphocytic Leukaemia.

**ENGOT - European Network of Gynaecological Oncological Trials Group.** We are collaborating with this group since 2018 starting with the ENGOT cx8 study, a phase 1b/2 open label trial of tisotumab vedotin in combination with other agents in patients with recurrent or stage IVB cervical cancer, which is now in follow-up. A new trial, ENGOT cx12 is currently in development, a randomized, open label, phase 3 trial of Tisotumab Vedotin versus investigator's choice chemotherapy in second or third line metastatic or recurrent Cervical Cancer, which we hope to open soon.

**GBG – German Breast Cancer Group.** In 2014 we were able to bring the PENELOP-B study to Ireland, this is a phase III study evaluating palbociclib (PD-0332991) in patients with HR-positive, HER2-normal primary breast cancer with high relapse risk after neoadjuvant chemotherapy, which is now after successful accrual in the follow-up phase. In 2020 we were asked to participate in a new breast cancer study addressing a similar patient population, SASCIA, a phase III post-neoadjuvant study evaluating Sacituzumab Govitecan in primary HER2-negative breast cancer patients with high relapse risk after standard neoadjuvant treatment. This study is now in development in Ireland.

**GEICAM** is a Spanish non-profit organisation which specialises in Breast Cancer clinical trials and Cancer Trials Ireland opened their FLIPPER trial for hormone receptor-positive metastatic breast cancer for Irish patients, which is now in the follow up phase. We are currently setting up a new trial, CARABELA, a Phase II, randomized, open-label trial to compare efficacy of standard chemotherapy vs. letrozole plus abemaciclib as neoadjuvant therapy in HR-positive/HER2-negative high/intermediate risk breast cancer patients.

### Industry collaborations

Since the inception of the organisation, we have established clinical research partnerships with many global pharmaceutical and biotechnology companies. In 2020 the study portfolio included studies from AbbVie, Astellas, Astra Zeneca, Bayer, BioProtect, Blueprint, Bristol Myers Squibb, Celgene, Chimerix, Clovis Oncology, Eisai, Exelixis, Glaxo Smith Kline, Incyte, IRIS, LOXO, Medivation, Merck/Serono, Millennium, MSD, Nordiv, Novartis, Onconova, Outcome Sciences, Pfizer, Puma Biotechnology, Radius Pharma, Regeneron, Roche and Sanofi. The breadth of studies includes early phase I/II clinical trials of novel anti-cancer agents through to large registration trials for more established treatments.



## Cancer trials research unit monitoring

The conduct of a clinical trial should be adequately monitored in order to ensure the reliability and robustness of the results. Monitoring of clinical trials is a requirement of ICH GCP, EU and national regulations. Monitoring activity is carried out on a study by study basis both in the individual cancer research unit and remotely. Each study undergoes a risk analysis, prior to the study being open to patients, which determines the level of monitoring activity and rationale for the chosen monitoring strategy. The risk-based monitoring plan contains detailed information on how the study will be monitored from the time of study initiation to study closure. The COVID pandemic required to develop adaptive strategies to facilitate continued trial conduct and develop resilience for clinical trial conduct in a pandemic reality. It can include the possibility of remote monitoring and close out which, with the support of the hospital, allows for the clinical trial to be monitored without the need to have staff visit the hospital.

The monitoring level can be a combination of on-site or remote and centralised monitoring activities as appropriate to the risk inherent to the type of study and other identified risks. Triggers for decreased or more frequent targeted on-site or remote monitoring visits can be identified in the monitoring plan. The monitoring level can also be determined on a site-by site basis depending on the previous or unknown experience of the investigational site.

## Research Unit staff around Ireland



**Erica Bennett**  
Bons Cork



**Fausta Barizaite**  
SVUH



**Debra O'Hare**  
CUH



**Cian Ronayne**  
CUH



**Amy Mahon**  
SVUH

## Audits

Number of days spent in 2020 preparing for and conducting audits and follow-up activity as well as active participation in external sponsor and third party audits and regulatory inspections both at our central office and at cancer trials research units around the country.

Audit Type	Preparation (days)	Audit (days)	Follow-up (days)
Regulatory Authority (HPRA) Inspection of Cancer Trials Ireland Central office	0	0	29.25
External Sponsor audit of Cancer Trials Ireland (central office)	0	0	5.5
Cancer Trials Ireland internal audit	1	13.5	6.5
Cancer Trials Ireland Audit of Research Units	19.5	14.5	39
Audit strategy/planning and audit/inspection readiness	5.5	-	-
<b>Total</b>	<b>25</b>	<b>28</b>	<b>80.25</b>

## Staff training (internal)

Training courses conducted by the central office training team along with attendance by central office staff and investigators/ investigational staff at research units.

Type of training	Number of Sessions	Number of attendees (Central Office staff)	Number of attendees (Research Unit Staff)
Quality and Training Overview	7	11	0
GCP: Basic/ Refresher Training (Central Office staff)	3	21	0
GCP: Full day course (Investigational Research Unit & Central Office staff)	1	6	6
Data Protection Training	4	26	0
Pharmacovigilance Training	4	11	0
Data Management Training	1	5	0
RECIST 1.1 training	1	16	0
Therapeutic Area training: Multiple Myeloma	1	33	0
Therapeutic Area training: Breast Cancer	1	32	0
Brexit & the implications for the transfer of personal data	1	11	6
Developing Clinical Research SOPs	1	38	0
Lessons learned from Inspection&Audit	1	44	0

## Pharmacovigilance

Pharmacovigilance activity	Number
SAEs received and processed by Cancer Trials Ireland * from MOM reviewed studies	194
Collaborative SAEs received (non inhouse studies) SAEs received through Cancer Therapy Evaluation Program's Adverse Expedited Reporting System (CTEP AERS) (includes follow-ups) / Med-Watch studies	37
SUSARs Entered onto Eudravigilance Database by Cancer Trials Ireland	94
PhV SOPs updated	0
Annual Development Safety Update Reports (produced in-house) distributed to relevant Ethics Committees and Competent Authorities by Cancer Trials Ireland	12
Annual Development Safety Update Reports (received from another sponsor) distributed to relevant Ethics Committees and Competent Authorities by Cancer Trials Ireland	10
Safety and clinical database reconciliations	31

## Staff training (external)

Significant external training courses attended by staff.

Date	Course	Attendees
23-Jan-20	iMedidata Coding	Data Management Team
31-Mar-20	RQA Webinar: COVID-19: 'GxP Insights on Building Resilience and Agility'	Quality and Training Manager
06-May-20	Business Continuity Institute – Restoration, Recovery, and Returning to the 'New Normal'	Quality Assurance Auditor
19-Jun 2020	<p>Medidata Webinar: Considerations for trial suspension &amp; restart during COVID-19 pandemic: the changing regulatory environment with respect to clinical trials in a COVID-19 world.</p> <ul style="list-style-type: none"> <li>Updated regulatory overview from the regional and national regulators.</li> <li>How COVID-19 has impacted trial participants and monitoring practices.</li> </ul> <p>Solutions to support decisions around study contribution, temporary halt or restart.</p>	Quality and Training Manager
25-Jun-20	RQA webinar on remote auditing	Quality and Training Associate Quality and Training Manager
17-Sep-20	HRB CRCI QWG Compliance Meeting	Quality and Training Manager
21-Sep-20	EMA Webinar: EMA Clinical Trial Information System Webinar: Dynamic Demo of Sponsor Workspace	Ethics&Regulatory Co-ordinator
14-16 Oct 2020	Clinical Project Management to Advance your Clinical Programs	Project Managers, Trial Coordinators and other roles.
21-Oct-20	MHRA Webinar: EU Exit and Post Transition Guidance: Clinical Trials Webinar covering aspects of clinical trials that will apply from 1 January 2021 including applying for a CTA, trial registration, results reporting, SUSAR reporting, IMP supply.	Quality and Training Manager Ethics&Regulatory Co-ordinator
23-Nov-20	EFGCP Webinar on Brexit	Quality Assurance Auditor
02-Dec-20	RQA Webinar: Risk-Based Auditing: Developing a QA Strategy and Execution Plan	Quality and Training Manager
Throughout 2020	EFGCP Webinars on a variety of topics related to the COVID-19 pandemic, e.g. Clinical Trials during the Pandemic, SDV, Re-starting trials, safety aspects, Clinical Study Reporting, Remote Audit&Inspection, Managing Deviations, Optimising Audits through Data Analytics, Country Comparisons, Medical Oversight, etc	Quality Assurance Auditor Quality and Training Manager

## Participation in conferences & meetings

Date	Meeting
28/02/2020	IACR
19/03/2020	WCG Webinar: Clinical Trials in the area of Covid19
31/03/2020	RQA Webinar (Mgt of trials during COVID-19)
03/04/2020	ENGOT Conference
07/04/2020	Access to Medicine Webinar: Adapt to Covid19
08/05/2020	Decentralized (Virtual) Clinical Trials - Myths and realities
13/05/2020	WCG Webinar: The Challenges of Developing Vaccines and Treatments fo Covid19
21/05/2020	RCSI Webinar series
04/06/2020	GCIG Harmonisation Meeting
04/06/2020	RCSI "Conversations that Matter.." webinar
11/06/2020	ETOP online conference
24/06/2020	AACR virtual meeting
30/06/2020	TMRN
01/07/2020	TMRN
13/07/2020	EFGCP webinar: Country comparsion of the effects of the pandemic on clinical research
13/07/2020	IPPOSI webinar "Patients Re-imagining Healthcare in Ireland"
16/07/2020	RCSI Leadership Masterclass: A Day in the Life - Lessons Learnt
27/07/2020	EFGCP webinar: Challenges and opportunities in Medical oversight
05/08/2020	AACR- Fauci recorded talk (COVID-19)
11/08/2020	NRG Oncology web conference
03/09/2020	TMRN webinar on NREC
09/09/2020	British Neurooncology meeting webinar day 1
09/09/2020	European Association for Neurooncology (EANO) conference day 1
09/09/2020	European Association for Neurooncology (EANO) conference day 2
10/09/2020	British Neurooncology meeting webinar day 2
21/09/2020	EMA Webinar: EMA Clinical Trial Information System Webinar: Dynamic Demo of Sponsor Work-space
22/09/2020	BTOG webinar: ESMO 2020 in an Hour
24/09/2020	EANO Annual general Meeting
28/09/2020	Webinar: The importance of breast cancer clinical research in Ireland organized by the ICS and hosted by Prof Cathy Kelly
28/09/2020	C.Kelly Webinar "The importance of breast cancer clinical research in Ireland"
28/09/2020	Webinar: The importance of breast cancer clinical research in Ireland organized by the ICS and hosted by Prof Cathy Kelly
07/10/2020	Charity Institute Ireland symposium day 1
08/10/2020	Charity Institute Ireland symposium day 2
14/10/2020	St Lukes Symposium: The Heritage Day
14/10/2020	HRB-TRMN Symposium day 1
14/10/2020	Webinar on de-escalation of breast cancer treatments by EORTC and BIG
15/10/2020	HRB-TRMN Symposium day 2
19/10/2020	EFGCP webinar - Independent Data Monitoring Committee IDMC/DSMB Challenges during COVID pandemic
21/10/2020	MHRA Webinar: EU Exit and Post Transition guidance webinar (Clinical Trials).
22/10/2020	IBEC HR Leadership Summit



29/10/2020	GCIG Harmonisation Meeting
30/10/2020	ENGOT Assembly
03/11/2020	GCIG Autumn 2020 Meeting - Ovarian Cancer Committee
04/11/2020	GCIG Autumn 2020 Meeting - Endometrial Cancer Committee
05/11/2020	GCIG Autumn 2020 Meeting - Cervix Cancer Committee
05/11/2020	The Gathering
12/11/2020	Irish Health Research Forum (IHRF)
16/11/2020	GCIG General Assembly
27/11/2020	All Ireland Colorectal Cancer Conference
30/11/2020	MSD Lung cancer webinar
30/11/2020	Lung Cancer Webinar-Breathing in a New Era
03/12/2020	MASC Conference
11/12/2020	Celebrating successful HRCI/HRB Joint Funding Scheme projects 2020"
05-06/11/2020	Gathering Around Cancer 2020
09- 10 /03/2020	ACDM
14- 15 /10/2020	HRB TRMN symposium
18- 19/11/2020	EU Cancer Summit
28-30 /10/2020	ENGOT Assembly

## Membership

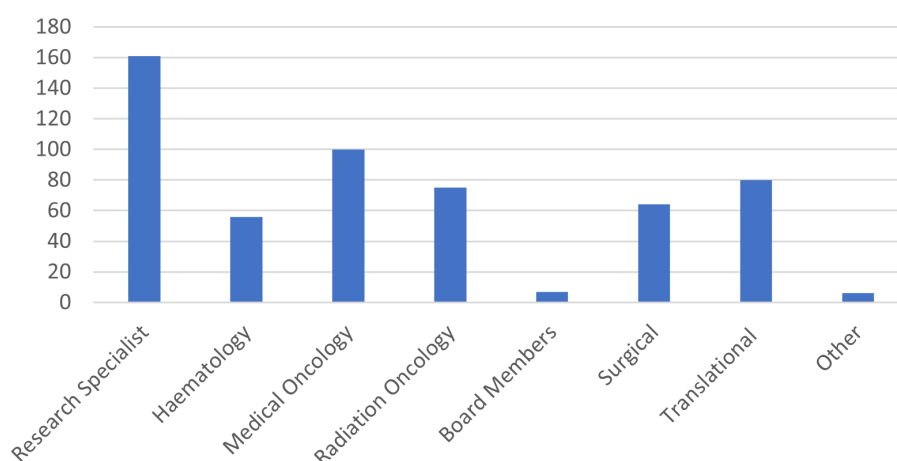
This metric records the number of registered Members of Cancer Trials Ireland.

Cancer Trials Ireland total membership on 31st December 2020 was 542. (37 new members joined during 2020).

During 2020 there were 240 Stakeholder members (this number is broken down between Patient Advocates and Industry).

Type	No.
Research Specialist	161
Medical Oncology	100
Surgical	64
Haematology	56
Radiation Oncology	75
Translational	80
Other	6

Cancer Trials Ireland Membership 2020



## Publications

This metric records the publications in peer-reviewed journals and abstracts accepted at top level international meetings based on the findings of trials the Members of Cancer Trials are, or have been, involved in.

Area	Peer Reviewed Journal Articles 2020	Abstracts: Poster/Oral Presentations 2020
Basket	2	2
Breast	8	6
Gastrointestinal	0	1
Genitourinary	7	3
Gynaecological	3	3
Head and Neck	1	0
Lung	2	0
Lymphoma and Haematological	0	0
Melanoma	0	0
Other	1	0
<b>Total</b>	<b>24</b>	<b>15</b>

\*Compiled from approval for/notification of abstracts received by Cancer Trials Ireland from Investigators. Potentially additional abstracts have been presented.

## Peer reviewed journal publications

### Basket

Cancer Trials Ireland Study Number: Short Name. 15-42: LOXO 101 Study

Hong, D. S., S. G. DuBois, S. Kummar, A. F. Farago, C. M. Albert, K. S. Rohrberg, C. M. van Tilburg, R. Nagasubramanian, J. D. Berlin, N. Federman, L. Mascarenhas, B. Geoerger, A. Dowlati, A. S. Pappo, S. Bielack, F. Doz, R. McDermott, J. D. Patel, R. J. Schilder, M. Tahara, S. M. Pfister, O. Witt, M. Ladanyi, E. R. Rudzinski, S. Nanda, B. H. Childs, T. W. Laetsch, D. M. Hyman & A. Drilon (2020) "Larotrectinib in patients with TRK fusion-positive solid tumours: a pooled analysis of three phase 1/2 clinical trials." *Lancet Oncol*, 21, 531-540.

Cancer Trials Ireland Study Number: Short Name. 15-43: CRQ Survey Study

Kearns, C., R. Feighery, J. Mc Caffrey, M. Higgins, M. Smith, V. Murphy, S. O'Reilly, A. M. Horgan, J. Walshe, R. McDermott, P. G. Morris, M. Keane, M. Martin, C. Murphy, K. Duffy, A. Mihai, J. Armstrong, D. M. O'Donnell, W. M. Gallagher & C. M. Kelly (2020) "Understanding and Attitudes toward Cancer Clinical Trials among Patients with a Cancer Diagnosis: National Study through Cancer Trials Ireland." *Cancers (Basel)*, 12.

### Breast

Cancer Trials Ireland Study Number: Short Name. 11-24: NSABP B47

Fehrenbacher, L., R. S. Cecchini, C. E. Geyer, P. Rastogi, J. P. Costantino, J. N. Atkins, J. P. Crown, J. Polikoff, J. F. Boileau, L. Provencher, C. Stokoe, T. D. Moore, A. Robidoux, P. J. Flynn, V. F. Borges, K. S. Albain, S. M. Swain, S. Paik, E. P. Mamounas and N. Wolmark (2020). "NSABP B-47/NRG Oncology Phase III Randomized Trial Comparing Adjuvant Chemotherapy With or Without Trastuzumab in High-Risk Invasive Breast Cancer Negative for HER2 by FISH and With IHC 1+ or 2." *J Clin Oncol* 38(5): 444-453.

Cancer Trials Ireland Study Number: Short Name. 14-12: MDV3100-12

Krop, I., V. Abramson, M. Colleoni, T. Traina, F. Holmes, L. Garcia-Estevez, L. Hart, A. Awada, C. Zamagni, P. G. Morris, L. Schwartzberg, S. Chan, A. Gucaip, L. Biganzoli, J. Steinberg, L. Sica, M. Trudeau, D. Markova, J.

Tarazi, Z. Zhu, T. O'Brien, C. M. Kelly, E. Winer & D. A. Yardley (2020) "A Randomized Placebo Controlled Phase II Trial Evaluating Exemestane with or without Enzalutamide in Patients with Hormone Receptor-Positive Breast Cancer." *Clin Cancer Res*, 26, 6149-6157.

Cancer Trials Ireland Study Number: Short Name. 10-11: Circulating miRNA's

McGuire, A., M. C. Casey, R. M. Waldron, H. Heneghan, O. Kalinina, E. Holian, A. McDermott, A. J. Lowery, J. Newell, R. M. Dwyer, N. Miller, M. Keane, J. A. L. Brown & M. J. Kerin (2020) "Prospective Assessment of Systemic MicroRNAs as Markers of Response to Neoadjuvant Chemotherapy in Breast Cancer." *Cancers (Basel)*, 12.

Cancer Trials Ireland Study Number: Short Name. 10-06: TROG DCIS

Olivotto, I. A., E. Link, C. Phillips, T. J. Whelan, G. Bryant, I. H. Kunkler, A. H. Westenberg, K. Purohit, V. Ahern, P. H. Graham, M. Akra, O. McArdle, J. J. Ludbrook, J. A. Harvey, J. H. Maduro, C. Kirkove, G. Gruber, J. D. Martin, I. D. Campbell, G. P. Delaney, B. H. Chua and B.-T. t. investigators (2020). "International comparison of cosmetic outcomes of breast conserving surgery and radiation therapy for women with ductal carcinoma in situ of the breast." *Radiother Oncol* 142: 180-185.

Cancer Trials Ireland Study Number: Short Name. 12-43: TRIO 022/ PALOMA-2

Rugo, H. S., R. S. Finn, K. Gelmon, A. A. Joy, N. Harbeck, A. Castrellon, H. Mukai, J. M. Walshe, A. Mori, E. Gauthier, D. R. Lu, E. Bananis, M. Martin & V. Diéras (2020) "Progression-free Survival Outcome Is Independent of Objective Response in Patients With Estrogen Receptor-positive, Human Epidermal Growth Factor Receptor 2-negative Advanced Breast Cancer Treated With Palbociclib Plus Letrozole Compared With Letrozole: Analysis From PALOMA-2." *Clin Breast Cancer*, 20, e173-e180.

Cancer Trials Ireland Study Number: Short Name. 06-31: TAILORx Study

Sparano, J. A., R. J. Gray, D. F. Makower, K. S. Albain, T. J. Saphner, S. S. Badve, L. I. Wagner, V. G. Kaklamani, M. M. Keane, H. L. Gomez, P. S. Reddy, T. F. Goggins, I. A. Mayer, D. L. Toppmeyer, A. M. Brufsky, M. P. Goetz, J. L. Berenberg, C. Mahalcioiu, C. Desbiens, D. F. Hayes, E. C. Dees, C. E. Geyer, J. A. Olson, W. C. Wood, T. Lively, S. Paik, M. J. Ellis, J. Abrams & G. W. Sledge (2020) "Clinical Outcomes in Early Breast Cancer With a High 21-Gene Recurrence Score of 26 to 100 Assigned to Adjuvant Chemotherapy Plus Endocrine Therapy: A Secondary Analysis of the TAILORx Randomized Clinical Trial." *JAMA Oncol*, 6, 367-374.

Cancer Trials Ireland Study Number: Short Name. 16-20: IBCSG 48-14 POSITIVE

Sun, Z., S. M. Niman, O. Pagani, A. H. Partridge, H. A. Azim, F. A. Peccatori, M. Ruggeri, A. Di Leo, M. Colleoni, R. D. Gelber, M. M. Regan & P. S. Committee (2020) "Estimation of historical control rate for a single arm de-escalation study - Application to the POSITIVE trial". *Breast*, 53, 1-7.

\*Cancer Trials Ireland author (member of the Positive Steering committee) listed in the appendix

Cancer Trials Ireland Study Number: Short Name. 12-09: CharactHer

Walsh, N., C. Andrieu, P. O'Donovan, C. Quinn, A. Maguire, S. J. Furney, G. Gullo & J. Crown (2020) "Whole-exome sequencing of long-term, never relapse exceptional responders of trastuzumab-treated HER2+ metastatic breast cancer." *Br J Cancer*, 123, 1219-1222.

## Genitourinary

Cancer Trials Ireland Study Number: Short Name. 15-21: The ExPeCT Trial

Brady, L., B. Hayes, G. Sheill, A. M. Baird, E. Guinan, B. Stanfill, T. Vlajnic, O. Casey, V. Murphy, J. Greene, E. H. Allott, J. Hussey, F. Cahill, M. Van Hemelrijck, N. Peat, L. Mucci, M. Cunningham, L. Grogan, T. Lynch, R. P. Manecksha, J. McCaffrey, D. O'Donnell, O. Sheils, J. O'Leary, S. Rudman, R. McDermott & S. Finn (2020) "Platelet cloaking of circulating tumour cells in patients with metastatic prostate cancer: Results from ExPeCT, a randomised controlled trial." *PLoS One*, 15, e0243928.

Cancer Trials Ireland Study Number: Short Name. 08-17: IMRT Prostate

Cullen, D., J. Bryant, A. Maguire, D. Medipally, B. McClean, L. Shields, E. Noone, S. Bradshaw, M. Finn, M. Dunne, A. M. Shannon, J. Armstrong, O. Howe, A. D. Meade & F. M. Lyng (2020) "Raman spectroscopy of lymphocytes for

## Peer reviewed journal publications

the identification of prostate cancer patients with late radiation toxicity following radiotherapy." *Translational Biophotonics*, e201900035, 2627-1850.

Cancer Trials Ireland Study Number: Short Name. 06-15/97-01: Proteomic Prostate study/Prostate

Keenan, L. G., N. Ibrahim, M. T. Dunne, M. Finn & J. G. Armstrong (2020) "The effect of anaemia on normal tissue toxicity and survival outcomes in prostate cancer treated with radical radiotherapy and neo-adjuvant androgen deprivation." *Br J Radiol*, 93, 20190577.

Cancer Trials Ireland Study Number: Short Name. 08-17: IMRT Prostate

Medipally, D. K. R., D. Cullen, V. Untereiner, J. Bryant, G. D. Sockalingum, T. N. Q. Nguyen, E. Noone, S. Bradshaw, M. Finn, M. Dunne, A. M. Shannon, J. Armstrong, A. D. Meade & F. M. Lyng (2020) "Effect of hemolysis on Fourier transform infrared and Raman spectra of blood plasma." *J Biophotonics*, 13, e201960173.

Cancer Trials Ireland Study Number: Short Name. 08-17: IMRT Prostate

Medipally, D. K. R., D. Cullen, V. Untereiner, G. D. Sockalingum, A. Maguire, T. N. Q. Nguyen, J. Bryant, E. Noone, S. Bradshaw, M. Finn, M. Dunne, A. M. Shannon, J. Armstrong, A. D. Meade & F. M. Lyng (2020) "Vibrational spectroscopy of liquid biopsies for prostate cancer diagnosis." *Ther Adv Med Oncol*, 12, 1758835920918499.

Cancer Trials Ireland Study Number: Short Name. 05-03: Spinal Cord Compression

Thirion, P. G., M. T. Dunne, P. J. Kelly, A. Flavin, J. M. O'Sullivan, D. Hacking, W. Sasiadek, C. Small, M. M. Pomeroy, J. Martin, O. McArdle, I. Parker, L. S. O'Sullivan, A. M. Shannon, A. Clayton-Lea, C. D. Collins, M. R. Stevenson, A. Alvarez-Iglesias, J. G. Armstrong & M. Moriarty (2020) "Non-inferiority randomised phase 3 trial comparing two radiation schedules (single vs. five fractions) in malignant spinal cord compression." *Br J Cancer*, 122, 1315-1323.

Cancer Trials Ireland Study Number: short name. 97-01: Prostate

Xie, W., M. M. Regan, M. Buyse, S. Halabi, P. W. Kantoff, O. Sartor, H. Soule, D. Berry, N. Clarke, L. Collette, A. D'Amico, R. A. Lourenco, J. Dignam, M. Eisenberger, N. James, K. Fizazi, S. Gillesen, Y. Loriot, N. Mottet, W. Parulekar, H. Sandler, D. E. Spratt, M. R. Sydes, B. Tombal, S. Williams, C. J. Sweeney and I. W. Group (2020). "Event-Free Survival, a Prostate-Specific Antigen-Based Composite End Point, Is Not a Surrogate for Overall Survival in Men With Localized Prostate Cancer Treated With Radiation." *J Clin Oncol* 38(26): 3032-3041.

## Gynaecological

Cancer Trials Ireland Study Number: Short Name. 11-29: ICON 8B

Blagden, S. P., A. D. Cook, C. Poole, L. Howells, I. A. McNeish, A. Dean, J. W. Kim, D. M. O'Donnell, J. Hook, E. C. James, I. R. White, T. Perren, R. Lord, G. Dark, H. M. Earl, M. Hall, R. Kaplan, J. A. Ledermann & A. R. Clamp (2020) "Weekly platinum-based chemotherapy versus 3-weekly platinum-based chemotherapy for newly diagnosed ovarian cancer (ICON8): quality-of-life results of a phase 3, randomised, controlled trial." *Lancet Oncol*, 21, 969-977.

Cancer Trials Ireland Study Number: Short Name. 10-12: ANZGOG-0701 symptom benefit study

Roncolato, F. T., R. L. O'Connell, F. Joly, A. Lanceley, F. Hilpert, L. Buizen, A. Okamoto, E. Aotani, V. Salutari, P. Donnellan, A. Oza, E. Avall-Lundqvist, J. Berek, T. Fehm, J. Ledermann, C. Roemer-Becuwe, M. R. Stockler, M. T. King and M. L. Friedlander (2020). "Predictors of progression free survival, overall survival and early cessation of chemotherapy in women with potentially platinum sensitive (PPS) recurrent ovarian cancer (ROC) starting third or subsequent line( $\geq 3$ ) chemotherapy - The GCIG symptom benefit study (SBS)." *Gynecol Oncol* 156(1): 45-53.

Cancer Trials Ireland Study Number: short name. 18-27: PORTEC 4a

van den Heerik, A. S. V. M., N. Horeweg, R. A. Nout, L. C. H. W. Lutgens, E. M. van der Steen-Banasik, G. H. Westerveld, H. A. van den Berg, A. Slot, F. L. A. Koppe, S. Kommoss, J. W. M. Mens, M. E. Nowee, S. Bijmolt, D. Cibula, T. C. Stam, I. M. Jurgenliemk-Schulz, A. Snyers, M. Hamann, A. G. Zwanenburg, V. L. M. A. Coen, K. Vandecasteele, C. Gillham, C. Chargari, K. W. Verhoeven-Adema, H. Putter, W. B. van den Hout, B. G. Wortman, H. W. Nijman, T. Bosse and C. L. Creutzberg (2020). "PORTEC-4a: international randomized trial of molecular



profile-based adjuvant treatment for women with high-intermediate risk endometrial cancer." *Int J Gynecol Cancer* 30(12): 2002-2007.

## Head and Neck

Cancer Trials Ireland Study Number: short name. 20-04: PRESERVE

Lang, P., J. Contreras, N. Kalman, C. Paterson, H. Bahig, A. Billfalk-Kelly, S. Brennan, K. Rock, N. Read, V. Venkatesan, J. Sathya, L. C. Mendez, S. D. MacNeil, A. C. Nichols, K. Fung, A. Mendez, E. Winkvist, S. Kuruvilla, P. Stewart, A. Warner, S. Mitchell, J. A. Theurer and D. A. Palma (2020). "Preservation of swallowing in resected oral cavity squamous cell carcinoma: examining radiation volume effects (PRESERVE): study protocol for a randomized phase II trial." *Radiat Oncol* 15(1): 196.

## Lung

Cancer Trials Ireland Study Number: Short Name. 12-24 ETOP BELIEF

Molina-Vila, M. A., R. A. Stahel, U. Dafni, N. Jordana-Ariza, A. Balada-Bel, M. Garzón-Ibáñez, B. García-Peláez, C. Mayo-de-Las-Casas, E. Felip, A. Curioni Fontecedro, O. Gautschi, S. Peters, B. Massutí, R. Palmero, S. Ponce Aix, E. Carcereny, M. Früh, M. Pless, S. Popat, S. Cuffe, P. Bidoli, R. Kammeler, H. Roschitzki-Voser, Z. Tsourtis, N. Karachaliou and R. Rosell (2020). "Evolution and Clinical Impact of EGFR Mutations in Circulating Free DNA in the BELIEF Trial." *J Thorac Oncol* 15(3): 416-425.

Cancer Trials Ireland Study Number: Short Name. 12-53: ETOP SPLENDOR

Peters, S., S. Danson, B. Hasan, U. Dafni, N. Reinmuth, M. Majem, K. G. Tournoy, M. T. Mark, M. Pless, M. Cobo, D. Rodriguez-Abreu, L. Falchero, T. Moran, A. L. Ortega Granados, I. Monnet, K. Mohoric, B. M. Sureda, D. Betticher, I. Demedts, J. A. Macias, S. Cuffe, A. Luciani, J. G. Sanchez, A. Curioni-Fontecedro, O. Gautschi, G. Price, L. Coate, R. von Moos, C. Zielinski, M. Provencio, J. Menis, B. Ruepp, A. Pochesci, H. Roschitzki-Voser, B. Besse, M. Rabaglio, M. E. R. O'Brien & R. A. Stahel (2020) "A Randomized Open-Label Phase III Trial Evaluating the Addition of Denosumab to Standard First-Line Treatment in Advanced NSCLC: The European Thoracic Oncology Platform (ETOP) and European Organisation for Research and Treatment of Cancer (EORTC) SPLENDOR Trial." *J Thorac Oncol*, 15, 1647-1656.

## Other (Policy)

Lewison, G., A. Gavin, K. McCallion, R. McDermott, R. Sullivan & M. Lawler (2020) "The 'Good Friday Agreement' and cancer research on the island of Ireland: Evidence for the impact of a tripartite cancer research partnership." *Eur J Cancer*, 129, 15-22.

# Abstracts: Oral and Poster Presentations

## Basket

Cancer Trials Ireland Study Number: Short Name. 15-42: LOXO 101 Study

Drilon, A. E., A. F. Farago, D. S-W. Tan, S. Kummar, R. S. McDermott, J. Berlin, J. D. Patel, M. S. Brose, S. Leyvraz, M. Tahara, B. M. Solomon, J. A. Reeves, M. M. Fellous, N. Brega, B. H. Childs, U. N. Lassen & D. S. Hong (2020). "Activity and safety of larotrectinib in adult patients with TRK fusion cancer: An expanded data set" Poster Presentation – ASCO Annual Meeting (*J Clin Oncol* 38: 2020 (no. 15 suppl; abstr 3610)).

Cancer Trials Ireland Study Number: Short Name. 15-42: LOXO 101 Study

Kummar, S., C. M. Van Tilburg, C. M. Albert, J. Berlin, A. F. Farago, R. S. McDermott, S. S. Bielack, F. P. Doz, S. G. DuBois, U. N. Lassen, S. Leyvraz, L. Mascarenhas, R. Nagasubramanian, K. N. Keating, C. Chirila, B. H. Childs, T. W. Laetsch, A. E. Drilon & D. S. Hong (2020). "Quality of life of adults and children with TRK fusion cancer treated with larotrectinib compared to the general population" Poster Presentation – ASCO Annual Meeting (*J Clin Oncol* 38: 2020 (no. 15 suppl; abstr 3614)).

## Peer reviewed journal publications

### Breast

#### Cancer Trials Ireland Study Number: Short Name. 15-16: Flipper

Albanell, J., M. T. M. Martínez, M. Ramos, M. O'Connor, L. De la Cruz-Merino, A. Santaballa Bertan, N. Martínez-Jañez, F. Moreno, I. Fernández Pérez, J. Alarcon Company, J. A. Virizuela Echaburu, J. De la Haba Rodríguez, P. Sánchez-Rovira, L. González-Cortijo, M. M. Margeli Vila, A. Sánchez Munoz, I. Garau Llinas, M. Casas, S. B. Montes & F. Rojo Todo (2020). "GEICAM/2014-12 (FLIPPER) study: First analysis from a randomized phase II trial of fulvestrant (F)/palbociclib (P) versus (vs) F/placebo (PL) as first-line therapy in postmenopausal women with HR (hormone receptor)+/HER2– endocrine sensitive advanced breast cancer (ABC)" Poster Presentation – ESMO (Ann Oncol 31, no 4 suppl; abstr LBA19).

#### Cancer Trials Ireland Study Number: Short Name. 10-06: TROG DCIS

Chua, B. H., E. Link, I. Kunkler, I. Olivetto, A. H. Westenberg, T. Whelan and G. Gruber (2020). "A randomized phase III study of radiation doses and fractionation schedules in non-low risk ductal carcinoma in situ (DCIS) of the breast (BIG 3-07/TROG 07.01)" Oral Presentation – SABCS (abstr GS2-04).

#### Cancer Trials Ireland Study Number: Short Name. 15-49: NeoTRIP

Bianchini, G., C-S. Huang, D. Egle, B. Bermejo, C. Zamagni, M. Thill, A. Anton, S. Zambelli, S. Russo, E. M. Cirelos, R. Greil, V. Semiglazov, M. A. Colleoni, C. M. Kelly, G. Mariani, L. Del Mastro, C. Smart, P. Valagussa, G. Viale & L. Gianni (2020). "Tumour infiltrating lymphocytes (TILs), PD-L1 expression and their dynamics in the NeoTRIPaPDL1 trial" Oral Presentation – ESMO (Ann Oncol 31, no 4 suppl; abstr LBA13).

#### Cancer Trials Ireland Study Number: Short Name. 12-43: TRIO 022/ PALOMA-2

Gelmon, K., J. M Walshe, R. Mahtani, A. A. Joy, M. Karuturi, P. Neven, D. R. Lu, S. Kim, P. Schnell, E. Bananis and L. Schwartzburg (2020). "Efficacy and safety of palbociclib (PAL) in patients (pts) with estrogen receptor-positive (ER+)/human epidermal growth factor receptor 2-negative (HER2-) advanced breast cancer (ABC) with preexisting conditions: A post hoc analysis of PALOMA-2" Poster Presentation – SABCS (abstr PS10-14).

#### Cancer Trials Ireland Study Number: Short Name. 14-11: PENELOPE-B

Loibl, S., F. Marmé, M. Martin, M. Untch, H. Bonnefoi, S-B. Kim, H. Bear, N. McCarthy, M. M. Olivé, K. Gelmon, J. G. Sáenz, C. M. Kelly, T. Reimer, M. Toi, H. S. Rugo, S. Seiler, V. Nekljudova, C. Denkart, M. Gnant, A. Makris, N. Burchardi and G. von Minckwitz (2020). "Phase III study of palbociclib combined with endocrine therapy (ET) in patients with hormone-receptor-positive (HR+), HER2-negative primary breast cancer and with high relapse risk after neoadjuvant chemotherapy (NACT): First results from PENELOPE-B" Oral Presentation – SABCS (abstr GS1-02).

#### Cancer Trials Ireland Study Number: Short Name. 15-34: Recurrence Score

McSorley, L. M., F. Al Rahbi, M. Tharmabala, D. Evoy, J. G. Geraghty, R. Prichard, J. Rothwell, D. McCartan, E. McDermott, M. M. Keane, J. Kennedy, S. O'Reilly, S. Millen, J. Crown, L. M. Smyth, C. M. Kelly, C. Quinn & J. M. Walshe (2020). "Real-world analysis of clinical and economic impact of 21-gene recurrence score (RS) testing in early-stage breast cancer (ESBC) in Ireland" Poster Presentation – ASCO Annual Meeting (J Clin Oncol 38: 2020 (no 15 suppl; abstr 540)).

### Gastrointestinal

#### Cancer Trials Ireland Study Number: Short Name. 12-38: TRI-LARC

Lee, C. L., S. Toomey, B. O'Neill and B. T. Hennessy (2020). "Serial ctDNA (circulating tumour DNA) for detection of genomic changes during neoadjuvant chemoradiotherapy (NACRT) in locally advanced rectal cancer (LARC)" Poster Presentation – ESMO (Ann Oncol 31, no 4 suppl; abstr 430P).

### Genitourinary

#### Cancer Trials Ireland Study Number: Short Name. 19-32: DASL HiCAP

Niazi, T., S. Williams, I. D. Davis, M. R. Stockler, A. J. Martin, W. Hague, K. Bracken, M. Gorzeman, F. Roncolato, S. Yip, L. Horvath, S. Sengupta, S. Hughes, R. S. McDermott, J. WF. Catto, N. Vapiwala, W. R. Parulekar & C. Sweeney (2020). "DASL-HiCAP (ANZUP1801): The impact of darolutamide on standard therapy for localized very

high-risk cancer of the prostate—A randomized phase III double-blind, placebo-controlled trial of adding darolutamide to androgen deprivation therapy and definitive or salvage radiation in very high-risk, clinically localized prostate cancer” Poster Presentation – ASCO Annual Meeting (J Clin Oncol 38, 2020 (no. 6 suppl; abstr TPS385)).

Cancer Trials Ireland Study Number: Short Name. 19-32: DASL HiCAP

Niazi, T., S. Williams, I. D. Davis, M. R. Stockler, A. J. Martin, K. Bracken, F. Roncolato, M. McJannett, L. Horvath, S. Sengupta, S. Hughes, R. McDermott, J. W. Catto, P. Kelly, N. Vapiwala, W. R. Parulekar, S. Morgan, R. A. Rendon & C. Sweeney (2020). “DASL-HiCaP: Darolutamide augments standard therapy for localised very high-risk cancer of the prostate (ANZUP1801). A randomised phase III double-blind, placebo-controlled trial of adding darolutamide to androgen deprivation therapy and definitive or salvage radiation” Poster Presentation – ESMO (Ann Oncol 31, suppl 4; abstr 694TiP).

Cancer Trials Ireland Study Number: Short Name. 07-11: SCC Retreat

Thirion, P., M. Dunne, I. Parker, C. Small, A. M. Shannon, A. Clayton-Lea, M. Parker, C. D. Collins, J. Coffey, N. Elbeltagi, D. Fitzpatrick, O. McArdle, M. Stevenson, A. Alvarez-Iglesias, M. Moriarty, O. Salib, C. Gillham, and J. G. Armstrong (2020). “Phase II Trial Evaluating Radiobiological Based Reirradiation Strategy for Patients with Malignant Spinal Cord Compression” Oral Presentation – ASTRO (Int J Radiat Oncol Biol Phys 108, issue 3, S33-34).

## Gynaecological

Cancer Trials Ireland Study Number: Short Name. 11-29: ICON 8B

Clamp, A. R., E. C. James, I. McNeish, A. Dean, J-W. Kim, D. M. O'Donnell, J. Hook, D. Gallardo-Rincon, C. Coyle, S. Blagden, J. D. Brenton, R. Naik, T. J. Perren, S. Sundar, A. Cook, J. Badrock, A. M. Awart, M. K. Parmar, R. S. Kaplan, J. A. Ledermann (2020). “ICON8: Overall survival results in a GCIG phase III randomised controlled trial of weekly dose-dense chemotherapy in first line epithelial ovarian, fallopian tube or primary peritoneal carcinoma treatment” Oral Presentation – ESMO (Ann Oncol 31, no 4 suppl; abstr 805O).

Cancer Trials Ireland Study Number: Short Name. 16-04: PRIMA

Mirza, M. R., A. Gonzalez Martin, W. Graybill, D. M. O'Malley, L. Gaba, O-W. S. Yap, E. M. Guerra, P. G. Rose, J. F. Baurain, S. A. Ghamande, H. Denys, E. Prendergast, C. Pisano, P. Follana, K. Baumann, P. Calvert, J. Korach, Y. Li, D. Gupta, B. J. Monk (2020). “Evaluation of an individualized starting-dose of niraparib in the PRIMA/ENGOT-OV26/GOG-3012 study” Poster Presentation – ASCO Annual Meeting (J Clin Oncol 38: 2020 (no. 15 suppl; abstr 6050)).

**Cancer Trials Ireland Study Number: Short Name. 16-04: PRIMA**

Monk, B. J., I. Romero, W. Graybill, C. Churrua, D. M. O'Malley, B. Lund, O-W. S. Yap, J-F. Baurain, P. G. Rose, H. Denys, S. A. Ghamande, C. Pisano, M. Fabbro, E. I. Braicu, P. Calvert, A. Amit, E. Prendergast, A. Milton, Z-Y. Zhang, A. Gonzalez Martin (2020). “Niraparib exposure-response relationship in patients (pts) with newly diagnosed advanced ovarian cancer (AOC)” Poster Presentation – ASCO Annual Meeting (J Clin Oncol 38: 2020 (no. 15 suppl; abstr 6051)).

## Plans for future period

In 2021 we will begin scoping and planning for the new Cancer Trials Ireland strategy (2022-2027). This will coincide with the HRB Cancer Trials Network grant period, which will allow Cancer Trials Ireland more flexibility via infrastructure funding.

The new strategy will be built around our existing pillars of Governance, Funding Model, Operational Capability, Clinical Capability, and Profile. These pillars will be underpinned by well-defined programmes of activity and an updated Vision and Mission for the organisation.

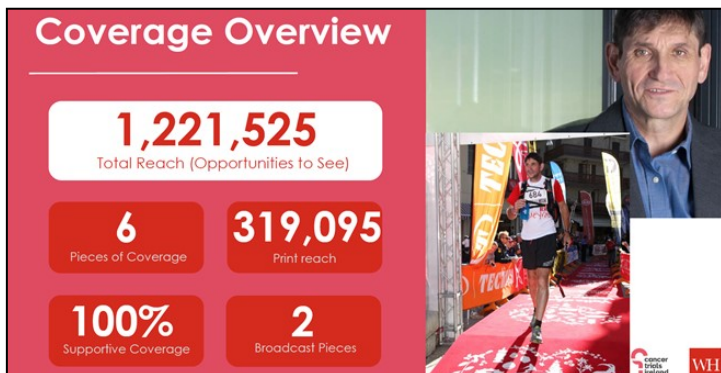
We are excited for the future.

## Communications

### Increasing awareness of Cancer Trials Ireland

A number of activities are undertaken during the year to increase the awareness of cancer trials and showcase the work that is being done across the country. These opportunities will continue to be pursued during the coming years. They include the following:

- **International Clinical Trials Day:** This is the organisation's annual set piece publicity event which results in a boost to the organisation's profile, the work of its members and contribution of patients. In 2020, we will collaborate with other key HRB-funded stakeholders (e.g. NREC) in celebrating International Clinical Trials Day to maximise the reach of our message to "Just Ask".
- **Mainstream media relations:** We are placing stories in local and national media on the opening of trials and announcing trial results. Features are also placed in national newspapers such as The Irish Independent.
- **Specialist media relations:** Details of trials are featured regularly in specialist medical press such as the Medical Independent, Cancer Professional and UPDATE Oncology and Haematology Journal.
- **Online:** In 2020 we launched a fully upgraded website. Regular updates on topical news and cancer trials listing are provided on our website ([www.cancertrials.ie](http://www.cancertrials.ie)) and regular posting on our Twitter and LinkedIn accounts, with the numbers of followers continuing to grow steadily.
- **DSSG Digest:** The DSSG Digest newsletter lists the latest news and up to date listing of open cancer trials. It is widely distributed within the community (including the media) both electronically and in hard copy.
- **Annual Review:** The publication of the organisation's Annual Review is another opportunity used to profile the organisation's successes and progress.
- **Conferences:** Attendances at conferences are used regularly to raise the profile of the organisation's work
- **Members newsletter:** We established a biannual newsletter for members on study news and updates.



### Implementing public and patient involvement (PPI)

- Several of the Disease Specific Sub-Groups (DSSGs) have patient consultants in attendance at closed meetings.
- The Patient Consultant's Committee (PCC) was set up as a sub-group of the Board in 2018. The Chair of the PCC now sits on the Board of Cancer Trials Ireland and a new Chair was appointed in 2020.
- Through the work of our Communications Office, we will promote our trials on our website, through conferences and on social media.
- In 2020 research commissioned by Cancer Trials Ireland uncovered strong public support for clinical trials.



## Fundraising: A letter to the family of the departed Pat Smullen

The text below is from a letter published on the Cancer Trials Ireland website on September 16th 2020.

It is with a very heavy heart that, on behalf of the staff and members of Cancer Trials Ireland, we put pen to paper in remembrance of our friend, and benefactor, Pat Smullen.

Pat was a friend like no other.

Almost a year ago to the day, Pat and his supporters raised a game-changing €2.6m for pancreatic cancer clinical trials. We would like to put this into context for you – just how dramatic and unusual this degree of fundraising is.



Earlier this year, Comic Relief reached out to the entire country raised almost €6m with the help of a host of celebs across several hours of primetime TV. Pat Smullen and the horse racing community raised almost half that - €2.6m – for pancreatic cancer clinical trials alone. People diagnosed with pancreatic cancer in Ireland will feel the benefit of it for years, if not decades, to come.

The low incidence of pancreatic cancer (around 560 people diagnosed in Ireland each year), the fact that it is not usually diagnosed early, and the relative difficulty of treating the disease effectively with the usual tools (chemotherapy; radiotherapy) make for a challenging, sparse research environment. But as a direct result of the funds Pat helped raise, Cancer Trials Ireland received nine research proposals this year. Three studies are now being advanced or explored, one of which will open in Ireland in a matter of weeks.

That is the work Pat has enabled us to do. But that is not all that Pat did for Cancer Trials Ireland. Last November, he helped us to raise more than €120,000 for ovarian and prostate cancer trials. Earlier this year, he gave us the go ahead to fund a Next Generation Sequencing machine (€100,000) for St Vincent's Hospital, Dublin. This machine will allow doctors to genetically sequence pancreatic cancer tumours, and other tumours, potentially opening up treatment options for thousands of people with all types of cancer. On a more personal level, Pat continually made himself available for interviews, photo calls, and phone calls - anything that might help people in a situation similar to his own.

It is a mark of the man that he had such a wide-ranging generosity. Pat's popularity – and humility – was and is legendary. It was truly remarkable, and inspiring, to see that these qualities can coexist with the drive and determination it takes to reach the very top of his demanding sport. Our thoughts, today and always, are with the Pat's wife Frances, his children Hannah, Paddy and Sarah, and his wider family.

Clinical trials offer patients very real, tangible, important benefits – but they can also provide something as vital as it is intangible: Hope. That is Pat's real gift to the people who come after him, who are diagnosed with pancreatic cancer.

The outpouring of love and support his efforts have generated give hope to us all.

Thank you, Pat

## Fundraising: Other

The Friends of Cancer Trial Ireland annual gala lunch, which normally take place in mid-November, was postponed in 2020 due to the COVID-19 pandemic. The organisers of the event are committed to re-establishing this event when it becomes possible once more, and they also committed to reaching out to previous donors on behalf of Cancer Trials Ireland in early 2021. We also enjoyed the continued support of the Oesophageal Cancer Fund who raised €50,000 for the NeoAEGIS study.

The horse racing community continued to support us in 2020, particularly through horse-leasing donations & horse prize-winnings. In 2020 a horse (Game-Set-Match won €10,000 for Cancer Trials Ireland, while the Belharbour point-to-point race donated funds and winnings totalling €40,000. We also continued to benefit from ad hoc donations from people and organisations touched by cancer and cancer trials, including: Arklow Cancer Support, Hayes Transport; The Coffey Group, and Ballina & Cloghan Anglers.

## Statement of income & retained earnings for the financial year ended 31 December 2020

	2020 €	2019 €
<b>Income</b>	3,955,939	3,637,546
Expenditure	(3,532,466)	(3,506,164)
<b>Surplus on ordinary activities before interest</b>	423,473	131,382
Interest receivable and similar income	2,288	3,928
<b>SURPLUS FOR THE FINANCIAL YEAR</b>	425,761	135,310
RETAINED EARNINGS AT THE BEGINNING OF THE FINANCIAL YEAR	533,914	398,604
<b>RETAINED EARNINGS AT THE END OF THE FINANCIAL YEAR</b>	959,675	533,914

Income and expenditure are all derived from continuing operations.

## Balance Sheet as at 31 December 2020

	2020 €	2019 €
<b>Fixed Assets</b>		
Tangible assets	37,283	25,379
<b>Current Assets</b>		
Debtors	2,708,930	2,906,087
Cash and cash equivalents	5,116,863	4,130,470
	7,825,793	7,036,557
<b>Creditors: Amounts falling due within one year</b>	(6,903,401)	(6,528,022)
<b>Net Current Assets</b>	922,392	508,535
<b>Net Assets</b>	959,675	533,914
<b>Reserves</b>		
Retained earnings	959,675	533,914
	959,675	533,914

The financial statements have been prepared in accordance with the small companies regime and were approved and authorised for issue by the Board of Directors on the 9<sup>th</sup> of November 2021 and signed on its behalf by:



Darren Byrne  
Director



Deirdre Somers  
Director

\*Full copy of financial statements for 2020 at [www.cancertrials.ie](http://www.cancertrials.ie)



*Together, we're finding  
answers to cancer.*